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Via Federal Express

Karin Ferriter
Office of Patent Legal Administration
United States Patent and Trademark Office
Crystal Plaza 3, Room 3D25
Washington, D.C. 20231

David T. Read
Health Assessment Policy Staff
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: Patent Term Extension for Relpax®

Dear Ms. Ferriter and Mr. Read:

By letter dated March 14, 2003, the PTO has asked FDA for information relating to Pfizer's pending patent-term-extension application for the recently-approved migraine medication, Relpax®. In addition to requesting confirmation of certain basic facts about Pfizer's application, the PTO's letter asks FDA to identify the "active ingredient" of Relpax® within the meaning of 35 U.S.C. § 156. Specifically, the PTO's letter asks:

Is the active ingredient of RELPAX® eletriptan (as suggested by the Approval letter dated December 26, 2002) or is it eletriptan hydrobromide (as stated in the "NMEs Approved in Calendar Year 2002" and the "Prescription and Over-the-Counter Drug Product List—22nd Edition Cumulative Supplement Number 12: dated December 2002")?

Pfizer is grateful to the PTO for copying us on this correspondence, and for providing Pfizer with an opportunity to address the question raised. As set forth below,

Pfizer submits that for purposes of patent term extension the “active ingredient” of Relpax®, within the meaning of 35 U.S.C. § 156(f), is eletriptan.¹

Section 156 provides for the extension of a patent claiming a “product” if, among other conditions, “the product has been subject to a regulatory review period before its commercial marketing or use” and “the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred . . .” 35 U.S.C. § 156(a)(4), (5). For purposes of section 156, a pharmaceutical “product” is defined as “the active ingredient” of a new drug “including any salt or ester of the active ingredient . . .” 35 U.S.C. § 156(f)(1), (2). The PTO and FDA jointly administer the legislated scheme for patent term extensions, with FDA’s role being to determine the applicable “regulatory review period” for pharmaceutical “products.” 35 U.S.C. § 156(d)(1), (2)(A)(ii).

FDA has issued a regulation defining the “active ingredient” of a pharmaceutical “product” for purposes of patent term extension. This regulation, 21 C.F.R. § 60.3(b)(2), provides that “active ingredient” means “any component that is intended to furnish pharmacological activity . . .” In the case of Relpax®, the active component of the drug molecule is eletriptan. The hydrobromide component of the molecule has no therapeutic activity, and thus is not properly considered to be part of the “active ingredient.” *See also Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 54 Fed. Reg. 50338, 50358 (1994) (for purposes of Hatch-Waxman data exclusivity, “The term ‘active ingredient’ as used in the phrase ‘active ingredient (including any salt or ester of the active ingredient),’ means active moiety.”); 21 C.F.R. § 314.108(a) (“*Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, or other noncovalent derivative of the molecule, responsible for the physiological or pharmacological action of the drug substance.”).

Although, as the PTO’s letter notes, FDA has identified the “generic name” of Relpax® as “eletriptan hydrobromide” in two published drug approval lists, those publications are not dispositive of the question the PTO has raised. FDA uses generic drug names in drug labeling and for therapeutic equivalence ratings. In those contexts, proper identification of the therapeutically inactive elements of a drug molecule is appropriate because those elements may affect drug stability, solubility, or bioavailability. Thus, there is a specific regulatory reason to identify the salt or ester form of a drug within the product’s generic name.

The “active ingredient” of a drug for purposes of patent term extension is textually and conceptually distinct from the drug’s generic name. Whereas a generic name is used to convey information important to drug usage and generic drug substitution, patent extension serves the specific legislative purpose of ensuring adequate

¹ Pfizer agrees with the PTO’s preliminary conclusion, as stated in the March 14 letter, that “the subject patent would be eligible for extension of the patent term” regardless of how FDA answers the quoted question.

incentive for pharmaceutical innovation. Moreover, the term “active ingredient” is used differently in the patent extension statute compared with its usage in the statutory provisions governing drug approval. In the context of the patent extension statute, “active ingredient” is conjoined with the phrase “(including any salt or ester of the active ingredient).” This gives “active ingredient” a broader meaning than when the term appears alone in statutory provisions governing drug approval (e.g., 21 U.S.C. §355(j)(2)(A)). In light of these important differences in usage and context, FDA properly interprets “active ingredient” for purposes of patent extension differently than it interprets “active ingredient” for purposes of drug labeling or drug approval. *See Abbott Labs. v. Young*, 920 F.2d 984, 987 (D.C. Cir. 1990); *see also Baker-Norton Pharm., Inc. v. FDA*, 132 F.Supp.2d 30, 35 (D.D.C. 2001) (noting that “it is not unusual for the same word to be used with different meanings in the same act”).

In 21 C.F.R. § 60.3(b)(2), FDA has provided that for purposes of patent extension, the term “active ingredient” is best understood to mean a drug’s active moiety: that is, its therapeutically active component. As noted, FDA similarly interprets “active ingredient” as “active moiety” for purposes of administering Hatch-Waxman data exclusivities. Applying FDA’s regulations in this case, the correct answer to the PTO’s question is that the “active ingredient” of Relpax® is eletriptan, which is the active moiety of Relpax®.²

Pfizer would be pleased to address any other questions the PTO or FDA has concerning this matter.

Sincerely,



cc: A. David Joran

² Although the recent decision in *Pfizer Inc. v. Dr. Reddy’s Labs., Ltd.*, No. 02-CV-2829, 2002 WL 31833744 (D.N.J. Dec. 17, 2002) rejected an argument that “active ingredient” for purposes of patent extension refers to a drug’s active moiety, Pfizer has appealed that decision on the basis that it incorrectly construes and applies section 156 and relevant court decisions. A decision by the Federal Circuit on this appeal (Nos. 03-1227 & 03-1258) is expected later this year.